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EXAMINER

GARCIA, MAURIE E

ART UNIT

PAPER NUMBER

1627

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7

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary

Application No.
09/754,958

Applicant(s)

Auer et al

Examiner
Maurie E. Garcia, Ph. D.

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jan 29, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-11 is/are pending in the application

4a) Of the above, claim(s) 1, 2, and 6-11 is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 3-5 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

20) ☐ Other:

DETAILED ACTION

1. The Responses filed January 29, 2002 and August 10, 2001 and (Papers No. 6 & 4, respectively) are acknowledged. No claims were amended, added or cancelled.

Therefore, claims 1-11 are pending.

Election/Restriction

2. Applicant's election with traverse of Group III (claims 3-5) in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1, 2 and 6-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Election was made without traverse in Paper No. 4.

4. Applicant's election with traverse of the species denoted EX (last compound in claim 5) is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement with respect to the election of species, the election has been treated as an election without traverse (MPEP § 818.03(a)) with respect to the species.

5. All of the claims in Group III read on the elected species; therefore, claims 3-5 are examined on the merits in this action.

6. Applicant's specifically elected species was searched and was not found in the prior art. Thus, the search was expanded to non-elected species. See MPEP § 803.02:

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

The compounds of claim 5 are free of the prior art with respect to the B-C-D'-E, B-E-C, B-E-D'-C and B-D-E-C portions depicted therein. However, this claim is rejected under 35 USC 112, see below.

Priority

7. Applicants are requested to amend the first line of the specification to update the status of the priority documents.

Information Disclosure Statement

8. The Information Disclosure Statement (IDS) filed on February 12, 2001 is noted. The cited references that are in a non-English language are considered to the extent of

applicant's statement of relevance and the examiner's limited understanding of the language.

Specification

9. The Abstract of the disclosure is objected to because of undue length. Correction is required. See MPEP 608.01 (b) and 37 CFR 1.72 (cited below):

37 CFR 1.72. Title and abstract: (b) A brief abstract of the technical disclosure in the specification must commence on a separate sheet, preferably following the claims, under the heading "Abstract" or "Abstract of the Disclosure." The abstract in an application filed under 35 U.S.C. 111 may not exceed 150 words in length. The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure. The abstract will not be used for interpreting the scope of the claims.

10. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Furthermore, in chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species

could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

11. Also, the specification contains "Legends to Figures" as opposed to the standard "Brief Description of the Drawing(s)". This adds confusion to the instant case. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

12. The use of the trademark "Tentagel" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any

manner which might adversely affect their validity as trademarks. The lengthy specification has not been checked to the extent necessary to determine the presence of all errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

13. Claims 3 and 4 are objected to because of the following informalities:

The claims contain more than one period (“.”) which is not permitted. See

MPEP 608.01(m) Form of Claims (emphasis added):

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with “I (or we) claim,” “The invention claimed is” (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the Technology Center (TC) technical support staff. ***Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations.*** See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995).

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to compounds "represented by formula (II – III)", where the formulas are set forth as "A-B-D-C-D'-E (Formula (II))" and "A-B-D-E-D'-C (Formula (III))". For claims 3 and 4, the following applies: (1) no specific linkage sites between each of the moieties are depicted whatsoever and (2) several portions of this molecule are set forth in only functional terms. For example, claim 3 recites that A is "a solid support selected from standard materials applied in solid phase and solution phase organic chemistry". These supports are further defined in claim 4; however, the limitations set forth on the supports in this claim are vague and open-ended. Furthermore, the claims define the E portion of the claimed compounds as "the molecule to be investigated". There are a virtually unlimited number of compounds that would fall within this claimed genus. The "molecule to be investigated" could encompass a wide variety of different moieties of varying structure. Moreover, the B portion of the claimed molecules is defined only as "a linker allowing cleavage of fluorescent conjugates of formula (II – III)". For claim 5, it is recognized that this claim defines specific B-C-D'-E, B-E-C, B-E-D'-C and B-D-E-C portions of the compounds. However, the claim does not define how these compounds are to be attached to the solid support (A).

Applicant's claimed scope represents only an invitation to experiment regarding possible compounds of formula (II – III) and portions thereof that have the claimed functions.

The present application fails to describe sufficient examples of compounds of formula (II – III) that are within the scope of the presently claimed invention. The instant description discloses the preparation of only a very limited number of compounds of formula (II – III)". The instant description also discloses only a limited number of examples of how the instant portions of the molecules (A, B, C, D, D' and E) can be linked together to form such compounds.

With respect to adequate disclosure of the scope of the presently claimed generic applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding disclosure. For adequate disclosure, like enablement, requires *representative examples* which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention*. See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure.

Therefore it is deemed that the disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that the structural features of the exemplified compounds do not constitute support for the claimed genus or a substantial portion thereof.

16. Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds comprising *specific* A, B, C, D, D' and E fragments with *defined structures* and *defined linkage sites*, does not reasonably provide enablement for compounds containing **any** A, B, C, D, D' and E fragments that are linked in **any** way. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might practice this invention with *specific* A, B, C, D, D' and E fragments having *defined linkage sites* and *defined structure*; however, there is insufficient guidance as to how to make/use compounds comprising **any** A, B, C, D, D' and E fragments that are linked in **any** way. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: Applicant's claims are directed to compounds "represented by formula (II – III)", where the formulas are set forth as "A-B-D-C-D'-E (Formula (II))" and "A-B-D-E-D'-C (Formula (III))". For claims 3 and 4, the following applies: (1) no specific linkage sites between each of the moieties are depicted whatsoever and (2) several portions of this molecule are set forth in only functional terms. Such represents very broad scope. It is noted that claim 5 recites specific fragment structures (B-C-D'-E, B-E-C, B-E-D'-C and B-D-E-C). However, the specific linkage to the solid support (A) and the nature of the solid support itself are not set forth in this claim. This also represents broad scope.

(3 and 5) The state of the prior art and the level of predictability in the art: Fluorescent conjugate compounds were well known at the time of filing; however, only limited numbers of such compounds were known and the specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of *any* compound of formula (II – III) defined as "A-B-D-C-D'-E (Formula (II))" and "A-B-D-E-D'-C (Formula (III))" that might have this function. The structures of possible variants are sufficiently diverse and one of ordinary skill

would not be able to predict their structures. The limitation that the compounds comprise several linked fragments adds to the unpredictability because each portion of various structure would require completely different linkage strategies. Even for the claims that recite specific fragment structures, it would not be predictable how to link any and all such fragments to any and all solid supports. Each support requires a different linkage strategy. Moreover, portions of the claimed compounds that are defined functionally could have a wide variety of structures with various sites that would be possible for linkage. One of ordinary skill could not guess, *a priori*, how to make and use **any** such compounds as one could not necessarily predict the linkage site and structure in the absence of any guidance without undue experimentation. Applicant's claimed scope of compounds represents only an invitation to experiment regarding possible fragments (A, B, D, D' and E) with undefined structure and linkage sites.

(4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have only provided examples of very specific compounds that comprise structurally defined fragments linked in a defined way. No generic strategy for determining the structure of each of the fragments and linkage sites is given. Specifically, the instant specification fails to identify that

structure which is required for the claimed activity. The teachings of the instant specification coupled with the examples only support specific compounds that are made up of fragments of *defined structure* linked at *defined linkage sites*.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the full scope of the claimed compounds. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. First, the claims contain the variable "C" which has not been defined in the claim.

Claims 3 and 4 recite merely "C is a compound selected from formula (I)" but does not define this formula in the claim. Correction is requested.

B. Claim 3 recites that A is "a solid support selected from standard materials applied in solid phase and solution phase organic chemistry". This limitation is unclear and does not particularly point out and distinctly claim the subject matter of the invention. Most importantly, the limitation states that "materials applied in ... solution phase organic chemistry" can be used. As A is defined as "a solid support", this is highly confusing.

C. Claim 3 defines the E portion of the claimed compounds as "the molecule to be investigated". This is deemed to be completely confusing. The instant claims are drawn to "Compounds represented by formula (II-III)". As the claims are drawn to a compound (not a method) and there is no other definition of the E portion of the molecule, applicant's intent is unclear.

D. Claim 4 recites the term "based" in several instances (i.e. "polystyrene based resins", "allyl based linkers"); this is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also

MPEP 2173.05(b). The addition of the word “based” extends the scope of the expression so as to render it indefinite.

E. Claim 4 contains a trademark (“Tentagel”) in the claim. See MPEP 2173.05(u):

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

F. Claim 4 also recites the limitations “functionalized surfaces” and “materials grafted with functionalized surfaces”, these are also relative terms which render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. That is, how functionalized are the surfaces, and with what?

G. Claim 4 also recites “low molecular weight compound”. The term “low” is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also MPEP 2173.05(b).

H. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: For

claims 3-4, the specific structures and linkage sites for each of the moieties. For claim 5, the particular linkage to solid supports (A) of unknown structure (such as "materials grafted with functionalized surfaces", see F above). Thus, one of ordinary skill would not know the metes and bounds of the claimed invention.

See also rejections under 112, first paragraph above.

Status of Claims/Conclusion

19. No claims are allowed.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.
21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
April 5, 2002



MAURIE E. GARCIA, PH.D.
PATENT EXAMINER